

Claims 26-44. The non-elected subject matter of process Claims 45-50 has been withdrawn from consideration, however, these claims are subject to possible rejoinder pending allowance of the product claims. There are no prior art rejections for anticipation, however the Office has issued a rejection under 35 USC § 103 for obviousness.

Claims 26-36 and 39-42 are rejected under 35 USC 103(a) based on the disclosure of Derrieu, et al. (US 5,527,783). It is the position of the Office that Derrieu, et al. teaches a composition that contains all of the components of the instant composition, thereby rendering the instant claims obvious. The Office acknowledges that Derrieu, et al. does not teach concentrations in the ranges claimed in generic Claim 26, however, it is the position of the Office that such differences are immaterial to patentability unless they are demonstrated to be a critical feature of the invention.

The applicants assert that Derrieu, et al. is not relevant to the patentability of the instant composition because it does not disclose: (1) compositions consisting of active agents which are not plant-based; (2) compositions with a disintegration time of 'less than one minute'; (3) compositions having an 'expanded structure'; or (4) compositions having an imperceptible texture upon contact with the buccal mucosal membrane.

The instant composition has a disintegration time **less than one minute**, preferably less than 30 seconds. In contrast, Derrieu, et al. teach a dissolution time which varies from **2-4 minutes** (see Example 3). The applicants assert that the faster dissolution characteristic of the claimed composition makes it a superior choice for ambulatory buccal or sublingual delivery of active principle. With this Response and Amendment, the applicants incorporate the broad

dissolution time limitation of Claim 39 into base Claim 26, thereby, further distinguishing the claimed composition from the prior art.

Regarding the lack of an '*expanded structure*' in the disclosure of Derrieu, et al., the applicants submit that the Derrieu, et al. disclosure is distinguished by the fact that it discloses plant-based oral lyophilizates which do not exhibit an *expanded structure*. This distinction may be attributable to the fact that lyophilizates are obtained by water sublimation. In contrast, the instant compositions have an *expanded structure*, which is attributable to the evaporation of water during preparation. Compositions which are formed on evaporation may be characterized by lower density. Thus, the reference compositions, which may be characterized by porous structure formed on lyophilization, may not render the instant compositions, exhibiting *expanded structure* formed on evaporation, obvious.

The applicants assert that the novel imperceptible texture of the instant composition upon contact with the buccal mucosal membrane offers a distinct advantage over the composition of Derrieu, et al. By virtue of its formulation and production process, the instant composition has a completely different texture wherein solid granules are not perceptible in the mouth. This characteristic enhances compliance in very young or old subjects in whom deglutition of solid forms poses a real problem.

Based on the aforementioned arguments, the applicants submit that Derrieu, et al. is not relevant to the patentability of the instant invention. Hence, reconsideration and withdrawal of the Obviousness rejection is respectfully solicited.

Finally, and for completeness, the applicants supply a Form PTO-1449 listing each reference disclosed and discussed in the Specification and well as provide English language equivalents of the references cited in the International Search Report, which Report is already acknowledged to be of record in the application. As will be noted, this submission calls a number of prior art references, which might be considered relevant, to the attention of the Office. The fact that these are in fact "Prior Art" and/or relevant to the prosecution is, however, not admitted. It is understood that, during examination, the Office has already made an independent search and identified any relevant prior art under 37 CFR § 1.104(a), as well as has had the benefit of the disclosure of the prior art discussed in the Specification and that identified in the International Search Report. Entry of this Information Disclosure Statement into the file of this application, initialing of each reference entry and making all of the references called to the Office's attention therein of record is respectfully solicited.

* * * * *

Accordingly, entry of the present amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,
THE FIRM OF HUESCHEN AND SAGE

By: 
G. PATRICK SAGE

Dated: October 20, 2003
Customer No.: 25,666
500 Columbia Plaza
350 East Michigan Ave.
Kalamazoo, MI 49007-3856
(269) 382-0030

Enclosure: Postal Card Receipt, our check number 71989 for \$950 for a three (3) month extension, Amended Listing of Claims, and Form PTO-1449 listing thirty one (31) references and copies of each reference.

THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.